NOV 2 6 2008

Transvivo®
INCORPORATED
3067 Research Drive
Richmond, CA 94806

Summary

This Summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the Omni-DL™ device.

1. **Company making the Submission:**

Name:	Transvivo, Inc.
Address:	3067 Research Drive
	Richmond, CA 94806 USA
Telephone:	510-223-1054 Voice
	510-785-8073 Fax
Contact:	J. Michael Delmage, Ph.D., MBA
e-mail:	mdelmage@transvivo.com

2. **Device Name:**

Trade/Proprietary Name:	Omni-DL™
Common/Usual Name:	High permeability hemodialysis system
Regulation Number:	876.5860
Product Code:	KDI
Review Panel:	Gastroenterology/Urology
Third Party Reviewed:	No
513g Number:	C060198

3. **Predicate Devices:**

Omni-DL™ device is substantially equivalent to other Dialyzer High permeability hemodialysis systems in the market such as the Prisma CFM System [K946279].

4. **Indications for Use Statement:**

Omni-DL™ Control Unit, Omni-DL™ CVVHDF Kit, 5 Liter Effluent Bag

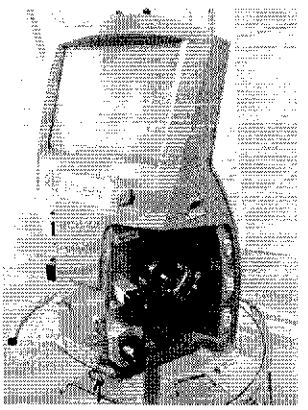
The Omni System, which consists of the Omni-DL™ Control Unit, Omni-DL™ CVVHDF Kit, and 5 Liter Effluent Bag, is intended for use in renal replacement therapies in a hospital or clinical setting where CRRT is administered. Four different solute and fluid management therapies are available:

- **SCUF** (Slow Continuous Ultrafiltration)
- **CVVH** (Continuous Veno-venous Hemofiltration)

- **CVVHD** (Continuous Veno-venous Hemodialysis)
- **CVVHDF** (Continuous Veno-venous Hemodiafiltration)

5. Description of Device:

The Omni-DL™ System (Omni System) provides continuous renal replacement therapies (hemodialysis, hemofiltration, hemodiafiltration, and ultrafiltration) in an intensive care setting for patients with acute renal failure and/or fluid overload. The Omni System consists of the Omni-DL™ Control Unit (Control Unit), the Omni-DL™ CVVHDF Kit (Omni Kit); a dedicated disposable tubing set which does not incorporate a hemofilter, and a separately packaged 5 Liter Effluent Bag.



The Omni System is a continuous renal replacement therapy (CRRT) system intended for patients with acute renal failure and/or fluid overload. The Omni is indicated for continuous solute and or fluid removal in patients with acute renal failure and/or fluid overload. Blood access for therapy with the Omni System is via established methods of vascular access. The Omni System is designed for use on patients in a hospital setting to provide the following treatments: SCUF (Slow Continuous Ultrafiltration), CVVH (Continuous Veno-Venous Hemofiltration), CVVHD (Continuous Veno-Venous Hemodialysis), and CVVHDF (Continuous Veno-Venous Hemodiafiltration).

6. Technological Characteristics:

The basic method of construction and materials is very similar. The methods of operation and indications for use are the same for the Omni-DL™ and the predicate device. Minor modifications were made to the Omni-DL™ System to incorporate current technology.

7. Non-clinical and Clinical Performance Data:

Non-clinical testing was performed on the Omni-DL™ System to demonstrate that the device met its functional and performance specifications. The Omni-DL™ System was subjected to extensive safety, software, and performance testing.

8. Conclusion:

Based on the testing and comparison to the predicate device the Transvivo, Inc., Omni-DL™ System has the same intended use, with similar technological characteristics. Transvivo, Inc., therefore posits that its device is equivalent in safety and effectiveness to the predicate devices.

Transvivo, Inc.

J. Michael Delmage 11/24/08
J. Michael Delmage, Ph.D., MBA
President and CEO

Revised per discussion with FDA. Dated: November 24, 2008

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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J. Michael Delmage, Ph.D., M.B.A.
President and CEO
Transvivo, Inc.
3067 Research Drive
RICHMOND CA 94806

Re: K080650
Trade/Device Name: Omni-DL™ Control Unit, Omni-DL™ CVVHDF Kit, 5 Liter Effluent Bag
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: October 27, 2008
Received: October 29, 2008

Dear Dr. Delmage:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number : K 80650

Device Name: Omni-DL™ Control Unit, Omni-DL™ CVVHDF Kit, 5 Liter Effluent Bag

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- **CVVHDF** (Continuous Veno-venous Hemodiafiltration)

Prescription Use **YES** (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080650